REMARKS

Claims 1-51 are pending in the present application. Claims 11, 12, 16, 21-25, 35, 36, 40, 47 and 50 have been withdrawn from further consideration, as being drawn toward non-elected subject matter. Claims 1-10, 13-15 and 17-20 have been cancelled without prejudice. Claim 27 has been amended to include the group CO_2R^7. Support for the amendment can be found in the specification on page 5, paragraph 0051. Claim 44 has been amended to correct a typographical error. No new matter has been added to the application.

Rejection Under 35 USC 103(a) Over DeLong

Claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 41-44, 48-49 have been rejected under 35 USC §103(a) as being unpatentable over DeLong (WO 99/50241).

The Examiner contends that DeLong exemplifies 11-oximyl-15-ethyl-18-phenyl-18-dinor-PG2 which purportedly "meets the formula of the instant claim when W is $(CH_2)_2$, R^1 is CO_2H, X is OH, Y is a bond, Z is an aromatic group, R^5 is C_2H_5 and H, R^6 is OH and H, p is 3, q is 0, a is a double bond, c is a single bond, and b is a double bond." Office action, page 3. The Examiner asserts it would have been obvious to one of ordinary skill in the art to exemplify the composition of DeLong as being administered to a mammal because DeLong teaches compositions being administered to a mammal and treating ocular disorders, hypertension, fertility control, nasal congestion, neurogenic bladder disorder, gastrointestinal disorders, dermatological disorders, and osteoporosis in mammals.

The Examiner further notes that method claims 26-34, 37-39, 41-44 and 48-49 are directed to a method of treating hair loss comprising administering to a mammal a composition comprising an active ingredient selected from the group consisting of oximyl and hydroxylamino prostaglandins having a specific functionality. The Examiner argues the following: "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. The prior art teaches administration to a mammal of compositions containing the same components as instantly claimed, which would inherently treat hair loss as instantly claimed." Office action, page 4.

Finally, the Examiner asserts that while the limitation of claim 18 is not explicitly taught, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the prostaglandins of DeLong in the amount recited in instant claim 18 because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

To establish a *prima facie* case of obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings; 2) there must be a reasonable expectation of success; and 3) the references must teach or suggest all of the claimed limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on Applicant's disclosure. *In Vaeck*, 947 F. 2d 422, 20 USPQ2d 1438 (Fed. Cir. 1991).

DeLong discloses compositions comprising prostaglandin analogs that may be used to treat "many medical disorders, including for example, ocular disorders, hypertension, fertility control, nasal congestion, neurogenic bladder disorder, gastrointestinal disorders, dermatological disorders, and osteoporosis." Page 36, paragraph 2. DeLong's compositions also treat bone disorders and glaucoma. DeLong makes no mention of treating hair loss.

The Examiner argues that if any of DeLong's compositions overlap with those in the present application, that the Applicant is precluded from claiming a new method of use for those compositions. Specifically, the Examiner requires that the Applicant prove the claimed properties were not inherent to the compositions of DeLong.

Inherency, however, is not a proper basis for an obviousness-type rejection. That which is inherent in the prior art, if not known at the time of the invention, cannot form a proper basis for rejecting the claimed invention as obvious under § 103. *In re Shetty*, 566 F.2d 81, 86, 195 USPQ 753, 756-57 (C.C.P.A. 1977). A copy of *Shetty* has been included for the Examiner's convenience. *Shetty* claimed a composition containing adamantane compounds and a method for using them to curb appetite in animals. The prior art taught structurally similar compounds for use as antiviral agents in recommended doses that corresponded to those claimed by *Shetty*. The

court found that although *Shetty's* "'amount effective to curb appetite' corresponds to or inheres in [the prior art's] amount to 'combat microbial infestation,' [it] does not persuade us of the obviousness of [*Shetty's*] method." *Id.* 566 F.2d at 86, 195 U.S.P.Q. at 756-7. "The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *Id.* 566 F.2d at 86, 195 U.S.P.Q. at 757. "[Inherency] is quite immaterial if ... one of ordinary skill in the art would not appreciate or recognize the inherent result." *Id.* (citing *In re Naylor*, 54 CCPA 902, 905-06, 369 F.2d 765, 768, 152 USPQ 106, 108 (1966). Nothing in DeLong suggests treating hair loss. DeLong disclosing similar prostaglandins useful for treating bone disorders and glaucoma is irrelevant with respect to obviousness.

Therefore, claims 26-34, 37-39, 41-44 and 48-49 are allowable. Reconsideration and allowance of these claims are respectfully requested.

Rejection Under 35 USC 103(a) Over DeLong and Nathanson

Claims 19, 45 and 46 were rejected under 35 USC 103(a) as being unpatentable over DeLong et al. as applied to claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 40-44, 48-49 in view of U.S. Patent No. 5,500,230 issued to Nathanson. Nathanson discloses a method for treating glaucoma by systemically administering a therapeutically effective amount of minoxidil to an individual. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the minoxidil of Nathanson to the composition of DeLong because both Nathanson and DeLong are directed toward treating glaucoma. Accordingly, the Examiner asserts that it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980).

Claim 19 has been cancelled without prejudice. Claims 45 and 46 depend from allowable claim 26, and therefore are allowable. Nevertheless, the Applicant respectfully disagrees with the application of *In re Kerkoven* to the present application. *In re Kerkoven*, as the Examiner correctly notes, held that it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is used for the very same purpose.

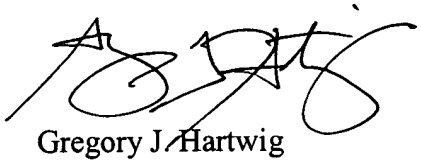
The Applicant submits that, indeed, the subject compositions of DeLong and Nathanson are both disclosed to be useful in the treatment of glaucoma (i.e., useful for the same purpose). However, the claims of the present application are not directed to the treatment of glaucoma. Rather, the claims of the present application are directed to the treatment of hair, and specifically hair loss in mammals. DeLong and Nathanson taken separately or combined do not teach or suggest the use of the compositions for the treatment of hair or hair loss. Thus, although the compositions of DeLong and Nathanson are useful for the same purpose, it would not have been obvious to a person of ordinary skill in the art to combine said compositions for a materially-different purpose. That which is inherent in the prior art, if not known at the time of the invention, cannot form a proper basis for rejecting the claimed invention as obvious under § 103. *In re Shetty*, 566 F.2d at 86, 195 USPQ at 756-57.

Therefore, claims 45 and 46 are allowable. Reconsideration and allowance of these claims are respectfully requested.

CONCLUSION

In view of the foregoing, the Applicant respectfully requests reconsideration and allowance of claims 26-34, 37-39, 41-46 and 48-49. Should any issues remain that preclude the allowance of the application, the Examiner is strongly encouraged to contact the undersigned at the telephone number identified below.

Respectfully submitted,



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LEXSEE 566 F.2D 81

IN THE MATTER OF THE APPLICATION OF BOLA VITHAL SHETTY

Appeal No. 77-515.

United States Court of Customs and Patent Appeals

566 F.2d 81; 1977 CCPA LEXIS 101; 195 U.S.P.Q. (BNA) 753

November 17, 1977, Decided

PRIOR HISTORY: [**1]

Serial No. 171,736.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant sought review of the decision of the Patent and Trademark Office Board of Appeals rejecting patent claims for an appetite suppressant.

OVERVIEW: Patent claims for an appetite suppressant for animals were rejected for obviousness on the ground that the antiviral agents used in the suppressant included the amount suggested to curb appetite. With modifications, the rejection was reversed on appeal. The molecular structure of the antiviral agent and the weight suppressant would not be a significant difference to a pharmaceutical chemist. However, use of the drug for curbing appetite had not been shown before. Although the new use was inherent in the previous invention, the use could not have been considered obvious because it was unknown.

OUTCOME: Rejection of applicant's claims for an appetite suppressant with a molecular structure similar to an antiviral agent was reversed because use of the drug for curbing appetite had not been shown before and could not be considered obvious.

LexisNexis(R) Headnotes

Patent Law > Nonobviousness > Tests & Proof of Obviousness

[HN1] The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.

COUNSEL:

Carl A. Hechmer, Jr., Edward A. Sager, Philadephia, Pa., attorneys of record, for appellant.

Joseph F. Nakamura, Washington, D.C., for the Commissioner of Patents; Jack E. Armore, Washington, D.C., of counsel.

OPINIONBY:

RICH

OPINION: [*82]

RICH, Judge.

This appeal is from that portion of the July 30, 1976, decision of the Patent and Trademark Office (PTO) Board of Appeals (board) rejecting claims 2-5, 51, and 52 in application serial No. 171, 736, filed August 13, 1971, entitled "Anorectic Adamantane Derivatives and Method of Using Same." The board rejected the claims

under *35 USC 103* on new grounds, as provided in *37 CFR 1.196(b)*, as obvious from Brake n1/ in view of Narayanan, n2/ Bernstein et al., n3/ and Bernstein. n4/ We affirm the rejection of composition claim 52 and reverse the rejection of method claims 51 and 2-5.

n1/ U.S. Patent No. *3,489,802*, issued Jan. 13, 1970, on application serial No. 610,779, filed Jan. 23, 1967.

n2/ U.S. Patent No. *3,501,511*, issued Mar. 17, 1970, on application serial No. 661,781, filed Aug. 21, 1967.

n3/ U.S. Patent No. *3,270,036*, issued Aug. 30, 1966, on application serial No. 493,899, filed Oct. 7, 1965.

n4/ U.S. Patent No. *3,320,249*, issued May 16, 1967, on application serial No. 470,930, filed July 9, 1965. [**2]

The Invention

The invention pertains to a method, as defined in claims 51 and 2-5, of curbing appetite in animals by administering certain adamantane compounds. n5/ The invention also pertains to the unit dosage form of a composition for curbing appetite comprising such an adamantane compound and a pharmaceutically acceptable carrier as defined in claim 52.

n5/ Adamantane is the trivial name assigned to tricyclodecane. Its structural formula can be represented in any of the following ways:

[Grapic omitted. See illustration in original.]

In the specification, appellant identifies his claimed compounds as follows:

or their pharmaceutically acceptable acid addition salts, wherein:

R1 = H, lower alkyl, aralkyl, aralkyl substituted with NH2, OH, OCH3, halogen, alkyl, NO2; phenoxyalkyl or phenoxyalkyl substituted with NH2, OH, OCH3, halogen, alkyl, or NO2; acyl such as formyl or acetyl.

R2 = H, lower alkyl, COO-lower alkyl, aralkyl, aralkyl substituted with NH2, OH, OCH3, halogen, alkyl, NO2; phenoxyalkyl or phenoxyalkyl substituted with NH2, OH, OCH3, halogen, alkyl, or NO2; acyl such as formyl or acetyl.

R1 and R2 can be joined together to form, with the nitrogen, [**3] a heterocyclic ring (e.g. -N O, -N, -N NH, -N N-C6H5-N S)

R3 = H, lower alkyl, or alkynyl

R4 = H, lower alkyl, or alkynyl

R5 = H, OH, halogen, or lower alkyl

R6 = H, OH, halogen, or lower alkyl

R5 and R6 together may represent a carbonyl oxygen

R7 = H, lower alkyl, halogen, hydroxy, alkoxy, amino or substituted amino, trifluoromethyl, sulfamyl, nitro, phenyl

R8, R9, R10, R11, R12 are any of R7

n = 0 to 4

m = 0 to 4 [*83]

Independent claim 51 defines the "method of curbing appetite in an animal which comprises administering to the animal an amount effective to curb appetite of a compound" of the above formula.

The References

Brake describes a process for improving the yield of alpha-methyl multicyclic methylamines, one of which is alpha-methyl-1-adamantanemethylamine, illustrated as:

[Grapic omitted. See illustration in original.]

and is described as being useful as an antiviral agent in animals.

Narayanan teaches adamantyl sulfonamide compounds, useful as antimicrobial agents, e.g., as antiviral agents, of the formula:

[Grapic omitted. See illustration in original.]

(I)

wherein R and R1 each is hydrogen, halogen, lower alkyl, phenyl or [**4] phenyl-lower alkyl, R2 is hydrogen or lower alkyl, R3 is hydrogen, lower alkyl, lower alkoxy, halogen or halo-lower alkyl and n is 0, 1 or 2, and salts thereof. [*84]

Narayanan also teaches the use of his compounds in dosages corresponding to those of appellant.

Bernstein et al. pertains to adamantyl biguanides of the formula:

[Grapic omitted. See illustration in original.]

and to acid-addition salts thereof.

In Formula I, R and R1 each is hydrogen, halogen, lower alkyl, phenyl or lower alkoxy, R2, R3 and R4 each is hydrogen, lower alkyl or phenyl-lower alkyl and n is 0 or 1.

These compounds are hypoglycemic agents effective in reducing blood sugar content in mammals.

The compounds of the Bernstein patent are illustrated by the following formula:

[Grapic omitted. See illustration in original.]

and to acid-addition and quaternary ammonium salts thereof.

These compounds are adamantyl derivatives of phenothiazines, therapeutically active as central nervous system depressants.

The Rejection

The examiner rejected appellant's claimed composition and method as obvious under *35 USC 103* in view of the teaching in Brake of administering to animals structurally [**5] similar adamantane derivatives "analogous" to those claimed. The Bernstein and Narayanan patents were cited to show similar compounds in the art. The examiner reasoned that the composition claim would have been obvious from the prior art because the respective compounds differ merely by a methylene group, i.e., the instant compounds have at least an ethylene link between the adamantane ring and the amine, whereas the prior art compound has a methylene link. This "minor molecular modification" was further asserted to be made obvious by the Bernstein and Narayanan patents, which disclose lower alkylene links between adamantane and other moieties and are directed to pharmaceutical uses.

The board treated the examiner's rejection as relying upon Brake alone and as citing the Bernstein and Narayanan patents to show the state of the art. The board did not sustain the rejection of claims 2-5, 51, and 52 as obvious from Brake alone because Brake's failure to disclose an amount of his compound effective as an antiviral agent renders unobvious the administration of "adjacent homologs of Brake's compound 'in an amount effective to curb appetite' * * *." Similarly, the board did not agree [**6] that appellant's composition in an "appetite curbing amount" would have been obvious from Brake alone.

Under *37 CFR 1.196(b)*, the board made a new ground of rejection under *35 USC 103* for obviousness from Brake in view of the Bernstein and Narayanan patents. The board agreed with the examiner that appellant's compounds having an ethylene linkage would have been obvious in view of Brake's corresponding adjacent homolog (methylene linkage). Relative to the method claims, the board found sufficient motivation in the prior art to administer Brake's compound and adjacent ethylene "homologs" as antiviral agents, and concluded [*85] that administering appellant's compounds in appetite-curbing amounts would have been obvious from Brake and Narayanan since the amounts suggested by Narayanan to achieve antiviral effects encompass the amounts intended and claimed by appellant.

The Arguments

Appellant contends that, after refusing to sustain the examiner's rejection on the basis of Brake alone, the board erred in rejecting the method claims by considering Narayanan in addition to Brake. Appellant argues that Narayanan's reference to dosage for treating viral infection is an improper [**7] basis for rejection. It is urged that the board mistakenly assumed that appetite-suppressant effects of appellant's compounds would be readily recognized from treating virus-infected animals with a related compound. It is also urged that the board ignored differences in treatments for viral infection and obesity, and that therefore Narayanan's dosage cannot be said to result in effective anorexia. Relative to the claimed composition, appellant states that there is an appreciable difference between the states that there is an appreciable difference between the structure of the compounds of the claim and the prior art compounds, and that the former would not have been obvious because the motivation to make the required structural variation is absent.

The solicitor responds by arguing that in the absence of comparative evidence of any unexpected difference in the properties of appellant's and Brake's compounds, the compounds of the claim would have been obvious from and unpatentable over the structurally closely related compound disclosed by Brake. It is argued that Brake and Narayanan render obvious appellant's pharmaceutical carrier and "unit dosage form." As to the method claims, [**8] the solicitor contends that Narayanan discloses adamantyl compounds as antiviral agents in dosages that correspond to and would suggest similar and inherently appetite-curbing amounts of the Brake antiviral compound. The solicitor supports the board position that because appellant's compounds are homologous and there is sufficient motivation in the prior art to administer Brake's compound as an antiviral agent, appellant's different purpose does not render the method claims unobvious.

OPINION

We note at the outset that the ethylene linkage of appellant's compound closest to the prior art (beta-(1-adamantyl)-alpha-methylethylamine) is referred to by the examiner as "analogous" to the methylene linkage of Brake's alpha-methyl-1-adamantanemethylamine and by the board as a "homolog." Since the appellant has not challenged either of these classifications, we proceed on the assumption that he accepts the inference that his

compounds, whether homologs or analogs, would be expected to have similar properties to the prior art compound. Whether the adamantyl compounds in question are properly classified according to the usual definitions of "homolog" and "analog," we shall not consider [**9] inasmuch as appellant has not argued the point.

The solicitor has taken the position that absent comparative evidence demonstrating any unexpected difference in the properties of the compounds, the claimed composition would have been obvious from and unpatentable over the structurally closely related compound disclosed in Brake. On the other hand, appellant contends that the presence of the ethylene rather than the methylene group constitutes "an appreciable difference in the claimed compound and the prior art compounds," and relies on *In re Taborsky, 502 F.2d 775, 183 USPQ 50 (CCPA 1974)* for support of his argument that without some teaching of motivation to make the required molecular variation, a finding of obviousness based on structural similarity is improper.

Regarding this issue of structural similarity, we agree with the solicitor and the PTO position. The examiner noted the difference of a mere methylene group between the compound of the claim and the prior art compounds, cited the Bernstein and Narayanan references showing the state of the art as prior art knowledge of use of lower alkylene links between adamantane and [*86] other moieties, and concluded that [**10] "this minor molecular modification would clearly be obvious to the pharmaceutical chemist." We do not accept appellant's contention that the adjacent alkylene link in question constitutes an "appreciable difference" in the compounds. We think that a person skilled in chemical and/or pharmaceutical arts would not hesitate to extend the alkylene linkage of the prior art compound. Further, we note that appellant's compound closest to the prior art and its synthetic preparation are disclosed in Narayanan as one of a group of compounds for producing his adamantyl sulfonamide. This leaves no room for doubt that the prior art knowledge renders appellant's compound structurally similar and provides sufficient motivation to make it.

Moreover, appellant has no basis for relying on *Taborsky, supra.* Unlike the present case, the prior art of record in Taborsky expressly limited the scope of "halogen" to exclude appellant's claimed fluorosalicylanilide compounds and stated "'several disadvantages in practice'" of free salicylanilides. *502 F.2d at 781, 183 USPQ at 55* (emphasis supplied). Appellant here has shown no such reason to preclude the conclusion that appellant's compounds are structurally [**11] similar to the prior art compounds.

Confronted with PTO evidence of obviousness, appellant has offered no evidence of unobviousness, as by showing an actual difference in properties between his compounds and the prior art compounds. *In re Hoch, 57 CCPA 1292, 428 F.2d 1341, 166 USPQ 406 (1970).* Appellant merely shows that his novel compounds are appetite suppressants whereas the reference compounds are not so known. Further, appellant has not indicated whether his compounds are antiviral, as is Brake's prior art compound. Presented with such an absence of comparative or other evidence with respect to the properties of the compounds and the claimed composition, we hold that composition claim 52 would have been obvious from and unpatentable over the prior art.

Regarding method claims 51 and 2-5, the solicitor agrees with the board that:

> * * * the compounds of claim 51 are obvious from and unpatentable over the corresponding Brake compound and the Narayanan disclosure of a dosage which corresponds to appellant's disclosed appetite curbing dosage (therefore, inherently appetite curbing). [Emphasis added.]

We cannot accept this conclusion. The issue here is whether the claimed [**12] method of curbing appetite would have been obvious. That appellant's "amount effective to curb appetite" corresponds to or inheres in Narayanan's amount "to combat microbial infestation" does not persuade us of the obviousness of appellant's method. As this court said in *In re Naylor, 54 CCPA 902, 905-06, 369 F.2d 765, 768, 152 USPQ 106, 108 (1966):*

> [Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result. * * *
>
> * * * we find nothing in the record which would afford one of ordinary skill reason to anticipate that a trial * * * [of the combined prior art teachings] would be successful in producing the polymer recited in the claims.

The Patent Office has failed to show a reasonable expectation, or some predictability, that Brake's compound would be an effective appetite suppressant if administered in the dosage disclosed by Narayanan. The mere hindsight assertion that corresponding dosages render appellant's method obvious is untenable. Prior to appellant's disclosure, none of the adamantane compounds in any of the references before us suggested a use, much less a dosage, [**13] for curbing appetite. What we said in *In re Spormann, 53 CCPA 1375, 1380, 363 F.2d 444, 448, 150 USPQ 449, 452 (1966),* relative to inherency applies equally here:

As we pointed out in *In re Adams, 53 CCPA 996, 356 F.2d 998, 148 USPQ 742* [(1966)], [HN1] the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown. [*87]

Accordingly, the decision of the board is affirmed as to claim 52 and reversed as to claims 51 and 2-5.

MODIFIED